

**TICK-ASSOCIATED RASH STUDY****ADULT CONSENT/ PARENTAL PERMISSION/ ADOLESCENT ASSENT FORM**

[NOTE: This form should be signed by patients 18 years of age or older who are able to give their legal consent. A parent or guardian of a minor child who is at least 3 years old should sign this form to give permission for the minor to enroll. Minor children ages 15-17 should sign this form to give their assent when a parent or guardian has given permission to enroll.]

**Introduction** Each year, the Centers for Disease Control and Prevention (CDC) hears of a mild illness that is a red, spreading skin rash. It occurs after tick bite in people living in the south or southeastern United States. These skin rashes usually look like the “bull’s eye” rash of Lyme disease. The germs that cause Lyme disease do not seem to cause the rash in the South. However, related germs might cause such infections. One of these related germs is named *Borrelia lonestari*. We will test for this germ and other germs as these tests become available during this study. The CDC Institutional Review Board will approve of tests for other germs before they are performed on your samples. Your doctor has asked you/your child to be in this research study because you/your child has a skin rash that may have come after a tick bite. The CDC is working with local doctors to do this research study. The CDC expects about 60 persons to be in this study over a period of three years.

**Purpose** The purpose of this study is to find the cause of the red, spreading skin rash that sometimes follows a tick bite in people living in the southern United States.

**Procedures** Your doctor will ask you/your child for two skin samples from the rash site. You/your child would not usually give skin samples to your doctor for your illness. The skin samples are only for this study. Your doctor also will ask you/your child for a blood sample. If the rash is no longer there, your doctor will ask you/your child for only a blood specimen.

a. **Blood** A physician, nurse, or medical technologist will take about 3 teaspoons of blood from your arm/your child’s arm at the first visit to your doctor’s office. They will take a second sample of about 2 teaspoons of blood 3 to 6 weeks later. Please make an appointment at your clinic today to schedule this second blood sampling. If you miss this second appointment, you will be called at home by a person from the clinic to reschedule it.

b. **Skin biopsy** A doctor will remove two small (less than 1/10 of an inch), round pieces of skin. The tool used to take a skin sample is sterile (free of germs) and disposable. The procedure for removing skin is called a punch biopsy. This is a standard minor medical procedure. The doctor will give two small, separate shots of a local pain killer with a needle just under the skin before the biopsy. Although these shots will reduce the pain from the biopsy, there still may be some discomfort during the procedure.

You/your child may participate in this study by giving only blood. You/your child may decide to give one skin sample instead of two.

The CDC will test your samples for signs of germs that might cause your/your child’s rash. Your doctor may request testing for Lyme disease. The CDC will do these tests, if asked, and report only the results of Lyme disease tests to your doctor.

### Long Term Storage of Specimens

After these initial tests have been performed, the CDC will store samples that are left in a confidential manner for future testing. After this study is over, CDC may do new tests for germs that might have caused your/your child's rash as these tests become available. The CDC will not report the results of these tests to your doctor or to you. CDC will not do human genetic testing or test for evidence of HIV (human immunodeficiency virus) infection of the samples that you or your child provide. If at a later date you change your mind, you may ask to remove these samples from long term storage and destroy them. If you choose to do so, please contact Dr. Barbara Johnson at the CDC at 970-221-6400.

### Risks and Discomforts

- a. **Blood drawing** Your doctor will take blood from your/your child's arm using a needle. Drawing the blood may hurt a little. It may also cause some bruising, bleeding, and slight soreness at the puncture site. There is a small chance you/your child could get germs in the spot where the blood was taken and become infected. If the area around the spot gets red and sore, you/your child would need to go to the clinic.
- b. **Skin biopsy** You/your child will have slight pain, redness, bleeding, or bruising at the biopsy site. A tiny scar may form there later. Usually, you/your child will not need stitches. There is a small risk of infection at the biopsy site. You will be given an instruction sheet that will tell you/your child how to help the wound to heal quickly and what to do if it does not.

**Benefits** You/your child will not directly benefit from the study. There is a benefit to society in general, through finding the cause of skin rash illness after tick bites in the southern United States.

**Confidentiality** The CDC will keep the data collection, informed consent/permission and assent forms in a locked file. Only study staff will be allowed to look at them. The CDC will keep the forms private as much as legally possible. To protect your/your child's privacy, we will keep records and samples under code numbers rather than by name. However, we will maintain a link between code numbers and the forms that we keep in locked files. Your/your child's name or other facts that might point to you/your child will not appear when we present this study or publish its results.

**Costs/Compensation** You will be responsible for the routine medical costs from your/your child's visit. These are costs that you would have if you/your child were not in the research study. You will have no charge for collection of blood samples (now and in 3 to 6 weeks) and skin samples. You will not pay for the research tests that CDC will do on these samples. If you are hurt as a result of being in this study, treatment will be provided by your health care provider. CDC does not normally pay for harm done to you as a result of being in a research study. Thus, you (or your insurer, Medicare, or Medicaid) will have to pay for any care that is needed.

**Right to Refuse or Withdraw** You/your child does not have to be in this study. Your doctor will give you/your child the usual care for your/your child's condition whether or not you/your child are in the study, or if you/your child leave the study later. To leave the study, please contact your doctor. You/your child may leave the study at any time.

**Persons to Contact** By signing this consent form and agreeing to be in this study, you are not giving up any of your rights. If you believe that you/your child have been harmed, please contact the Deputy Associate Director of Science at 1-800-584-8814 for information on your rights and advice on how to proceed. If the Deputy Director does not answer directly, leave a message including your name and phone number and protocol number 4278, so that you may be called back as soon as possible. The Deputy Director is not affiliated with this study in any way. If you have any questions, comments, or

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complaints about this study, please write or call Dr. Barbara J. B. Johnson, Bacterial Zoonoses Branch, Division of Vector-Borne Infectious Diseases, Centers for Disease Control and Prevention, P.O. Box 2087, Fort Collins, Colorado 80522, (970) 221-6400. If you decide at a later date that you wish to have your/your child's sample(s) destroyed, call Dr. Johnson.

I have read this consent/parental permission/assent form. I have been given a chance to ask questions and I feel that my questions have been answered. This study is voluntary. After choosing to be in this study, I/my child may leave it at any time. I have been told the risks and benefits to me/my child of being in this study. I have been told how to care for the biopsy site. I have been given a wound care sheet by my doctor.

I have checked the boxes for the parts of the study that I agree to for myself or for my child:

- ☐ Provide a blood sample today or as soon as possible
- ☐ Provide a second blood sample in 3-6 weeks
- ☐ Provide one skin sample from rash site today or as soon as possible
- ☐ Provide a second skin sample at the same time as the first sample
- ☐ Permit long-term storage and future testing of all samples (this is a requirement of enrollment)

Date\_\_\_\_ / \_\_\_\_ / \_\_\_\_

Please print \_\_\_\_\_  
(Full name of patient or parent/guardian)

Address \_\_\_\_\_  
Street City State Zip Code

Signature of patient or parent/guardian\_\_\_\_\_

***Patient copy***

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Date\_\_\_\_ / \_\_\_\_ / \_\_\_\_

Please print \_\_\_\_\_  
(Full name of patient or parent/guardian)

Address \_\_\_\_\_  
Street City State Zip Code

Signature of patient or parent/guardian\_\_\_\_\_